DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 23, 2016

Cynosure, Incorporated
Mr. Kevin J. O'Connell
Senior Regulatory Affairs Manager
5 Carlisle Road
Westford, Massachusetts, 01886

Re: K140719
Trade/Device Name: Picosure™ Workstation
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 27, 2014
Received: August 29, 2014

Dear Mr. O'Connell

This letter corrects our substantially equivalent letter of September 22, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140719

Device Name
Picosure™ Workstation

Indications for Use *(Describe)*
The PicoSure™ workstation is indicated for tattoo and benign pigmented lesions removal. The PicoSure™ workstation with the 3mm and 6mm hand pieces and the Focus Array are indicated for the treatment of acne scars and wrinkles in Skin Types I-IV.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) - Submitter Information	
Name	Cynosure, Inc.
Address	5 Carlisle Road Westford, MA 01886 USA
Phone number	978-367-8736
Fax number	978-256-6556
Establishment Registration Number	1222993
Name of contact person	Kevin J. O'Connell
Date prepared	April 4, 2016
807.92(a)(2) - Name of device	
Trade or proprietary name	PicoSure™ workstation
Common or usual name	laser
Classification name	Instrument, Surgical, Powered, laser
Classification panel	General and Plastic Surgery
Regulation	21 CFR 878-4810
Product Code(s)	GEX
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	PicoSure™ workstation K121346 PicoSure™ workstation K133364 Apogee Elite laser K034030
807.92(a)(4) - Device description	
	The PicoSure™ workstation is a high powered Alexandrite system that delivers laser energy in the 755-nm wavelength. The system consists of a console that houses the power supply, control electronics and the laser. Laser energy is delivered to the skin via an articulated arm. The laser is activated using a footswitch.
807.92(a)(5) Intended use of the device	
Indications for use	The PicoSure™ workstation is indicated for tattoo and benign pigmented lesions removal. The PicoSure™ workstation with the 3mm and 6mm hand pieces and the Focus Array are indicated for the treatment of acne scars and wrinkles in Skin Types I-IV.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

Characteristic	PicoSure™ Workstation (current submission)	PicoSure™ Workstation K133364	PicoSure™ Workstation K121346	Elite K034030
Laser Type	alexandrite	alexandrite	alexandrite	alexandrite
Wavelength	755nm	755nm	755nm	755 nm
Maximum Average Fluence	6.37 J/cm^2	6.37 J/cm2	6.37 J/cm^2	60 J/cm^2
Repetition Rate	Single pulse, or 1, 2.5, 5, or 10 pulse(s) per second (Hz)	Single pulse, or 1, 2.5, 5, or 10 pulse(s) per second (Hz)	Single pulse, or 1,2,5, or 10 pulse(s) per second (Hz)	1 to 5 pulse(s) per second (Hz)
Pulse Width	450ps-900ps	400ps-900ps	400ps-900ps	0.1 to 300 ms
Spot Sizes	Zoom 2-6 mm, Fixed 2, 3, 4, 6, 8, 10 mm with FOCUS lens array 3mm, 6 mm	Zoom 2-6 mm, Fixed 2, 3, 4, 6, 8, 10 mm with FOCUS lens array 3mm, 6 mm	Zoom 2-6 mm, Fixed 2, 3, 4, 6, 8, 10 mm	Fixed 3, 5, 7, 10, 12.5 and 15

807.92(b)(2) CLINICAL TESTS SUBMITTED

Discussion of Clinical Study:	The study was performed using 40 subjects ages 47 – 64 whose skin types ranged from I to IV. Before and after (4 months post treatment) photographs were evaluated by three blinded evaluators, who were able to identify correctly the before and after images in 91% of the 38 subjects that returned for 4 month evaluation. The mean improvement score using the Fitzpatrick Wrinkle Severity Scale at four months was 1.2 Therefore the primary objectives of the study: correct identification of post treatment photograph of 80% or greater and FWSS improvement score of "1" or greater, have been met. There were no deaths, serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) reported in this study. The events that were logged were typical reactions to laser treatments.

807.92(b)(3) Conclusion

Based on the clinical testing performed it was confirmed that use of the Picosure workstation resulted in a reduction of wrinkles without any serious adverse events or unanticipated adverse device effects